

Appl. No. 09/944,413
Ammdt. dated April 12, 2004
Reply to Office Action of January 13, 2004

REMARKS

In the Claims:

Claims 1-47 are cancelled herein without prejudice or disclaimer. New claims 48-54 have been added. New claims 48-54 do not encompass new matter and are supported at page 142 of the specification.

Request for Reconsideration:

Priority Determination

The Examiner has found that the instant application is supported by its parent application serial no PCT/US99/28301, filed 12/1/99. Although Applicants respectfully maintain that the proper priority date for the claimed invention is 12/3/97, the LaVallie *et al.* patent cited by the Examiner was filed November 14, 1996, which is earlier than Applicants' earliest priority date. Therefore, no further argument regarding priority is necessary at this point.

Formal Matters

The Examiner noted that on 5/21/03 Applicants submitted a new form PTO-1449 containing additional information regarding BLAST results, but also noted that according to the dates listed on the PTO-1449 form, the submitted BLAST results do not constitute prior art, the given dates being 1/8/2002. Applicants have filed simultaneously with this response a revised PTO-1449 form, listing the dates on which the BLAST results were entered. Applicants request that the Examiner review this new submission.

Rejections Over the Prior Art:

35 U.S.C. § 102(e)

The Examiner has rejected claims 35-47 under 35 U.S.C. § 102(e) as being anticipated by LaVallie *et al.*, U.S. Patent No. 5,846,770. Applicants have cancelled claims 35-47 herein without prejudice or disclaimer and therefore, respectfully request that this ground of rejection be withdrawn.

New claims 48-54 are directed to a method of hemoglobin induction comprising contacting a tissue or cell with a hemoglobin inducing polypeptide comprising the amino acid sequence of the polypeptide shown in Figure 4 (SEQ ID NO:7); the amino acid sequence of the polypeptide shown in Figure 4 (SEQ ID NO:7), lacking its associated signal peptide; the amino acid sequence of the extracellular domain of the polypeptide shown in Figure 4 (SEQ ID NO:7); the amino acid sequence of the extracellular domain of the polypeptide shown in Figure 4 (SEQ ID NO:7), lacking its associated signal peptide; or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 209508. At page 142, Example 36, Applicants disclose and enable both a hemoglobin inducing polypeptide, PRO243 (and the nucleic acid encoding it), and a method for selecting polypeptides and nucleic acids with hemoglobin induction ability.

LaVallie *et al.* does not anticipate the presently claimed invention because “[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate.” See *Elan Pharm., Inc. v. Mayo Found. For Med. Ed. and Research*, 2003 U.S. App. LEXIS 20195 (Fed. Cir. 2003). LaVallie *et al.* does not enable Applicants’ claimed invention because nowhere does LaVallie enable a method of inducing adult hemoglobin to switch to fetal hemoglobin. In fact, hemoglobin, much less hemoglobin induction, is not even mentioned anywhere in the LaVallie patent. Instead, LaVallie is directed to:

proteins that may be used in the treatment of bone, cartilage, other connective tissue defects and disorders, including tendon, ligament and meniscus, in wound healing and related tissue repair, as well as for treatment of disorders and defects to tissues which include epidermis, nerve, muscle, including cardiac muscle, and other tissues and wounds, and organs such as liver, brain, lung, cardiac, pancreas, and kidney tissue. The proteins may also be useful for the induction of growth and/or differentiation of undifferentiated embryonic and stem cells. (Abstract)

Hence, LaVallie *et al.* does not enable, and therefore, cannot anticipate the claims of the present application, directed to a method of inducing the switch from adult to fetal hemoglobin.

Moreover, although LaVallie discloses a nucleic acid and polypeptide nearly identical to Applicants' PRO243, LaVallie does not anticipate the present invention because LaVallie does not disclose any method for discovering the ability of its disclosed polypeptide to function in hemoglobin induction. According to the MPEP § 2131, "a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Hence, claims 48-54 are not anticipated by LaVallie *et al.*

35 U.S.C. § 103(a)

The Examiner has rejected claims 27-29 and 32-33 under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over LaVallie *et al.*, U.S. Patent No. 5,846,770. Applicants have cancelled claims 27-29 and 32-33 herein without prejudice or disclaimer and therefore, respectfully request that this ground of rejection be withdrawn.

As discussed above, LaVallie does not anticipate the presently claimed invention. In addition, LaVallie does not render the claimed invention obvious. As amended, the claims are directed to a method of hemoglobin induction comprising contacting a tissue or cell with a hemoglobin inducing polypeptide comprising the amino acid sequence of the polypeptide shown in Figure 4 (SEQ ID NO:7); the amino acid sequence of the polypeptide shown in Figure 4 (SEQ ID NO:7), lacking its associated signal peptide; the amino acid sequence of the extracellular domain of the polypeptide shown in Figure 4 (SEQ ID NO:7); the amino acid sequence of the extracellular domain of the polypeptide shown in Figure 4 (SEQ ID NO:7), lacking its associated signal peptide; or the amino acid sequence of the polypeptide encoded by the full-length coding sequence of the cDNA deposited under ATCC accession number 209508. As mentioned above, LaVallie does not suggest utilizing the disclosed nucleic acids and polypeptides in methods of hemoglobin induction. Rather, LaVallie discusses numerous other uses of the disclosed nucleic acids and polypeptides including in bone and cartilage formation assays (col. 1, lines 62-64), to demonstrate effects upon the growth and/or

Appl. No. 09/944,413

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differentiation of embryonic cells and/or stem cells (col. 1, lines 66-67), and in treating cell populations to enhance or enrich the growth and/or differentiation of cells (col. 2, lines 2-4). Hence, LaVallie neither teaches a method of hemoglobin induction comprising utilizing chordin or chordin-like proteins, nor does LaVallie suggest modifying its teachings to arrive at a method of hemoglobin induction.

Appl. No. 09/944,413

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CONCLUSION

Applicants respectfully submit that the application is now in condition for continued examination. Should the Examiner feel a discussion would expedite the prosecution of this application, the Examiner is kindly invited to contact the undersigned.

Respectfully submitted,

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